UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,793	09/06/2006	Martin Edward Lee Pickford	1450-02100	4654

62763 7590 03/02/2011

Tod T. Tumey
P.O. BOX 22188
HOUSTON, TX 77227-2188

EXAMINER	
LEADER, WILLIAM T	

ART UNIT	PAPER NUMBER
1723	

MAIL DATE	DELIVERY MODE
03/02/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,793	PICKFORD ET AL.	
	Examiner	Art Unit	
	WILLIAM T. LEADER	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-15,17,19-21,24,25,27-29 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-15,17,19-21,24,25,27-29 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 13, 2011, has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

3. Claims 13-15, 17, 19-21, 24, 25, 27-29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooper et al (US 5,211,832) in view of Pickford et al (WO 03/089023) or Ogle (US patent 6,267,782).

4. Applicant has amended independent claims 13 and 24 to recite additional limitations related to the characteristics of the layer produced by anodizing. The Cooper et al patent (hereinafter Cooper) is directed to a process for anodizing titanium and titanium alloys. See the abstract. In examples 6, 7 and 8 (column 6) a titanium workpiece was anodized in a phosphoric acid solution at an applied voltage of 75V or 100V for a period of time greater than 30 minutes. These are the same anodizing conditions disclosed and claimed by applicant. Because the process steps are the same, the characteristics of the anodized layer of Cooper would have been

expected to be the same as those of applicant's layer as recited in claims 13 and 24. Cooper discloses that the anodized layer formed on the titanium workpieces is excellent as a protective coating for surgical implants (column 6, lines 44-48).

5. The process recited by applicant in independent claim 24 differs from the process of Cooper by reciting adding ions of a biocidal metal by ion exchange. Pickford discloses a method for making a titanium implant by anodizing. Pickford recognizes that there is a risk of introducing infection when implanting a metal implant, and notes that it has been suggested to incorporate a biocidal material such as silver that can control infection without causing toxic effects to the patient (page 1, lines 14-19). Pickford discloses incorporating silver into a layer formed by anodizing a titanium implant by ion exchange. See page 5, lines 14-17.

6. The Ogle et al patent (US 6,267,782) is directed to a medical article such as an implant with an adhered antimicrobial metal to reduce the risk of infection. See the abstract. Implanted devices include articles that are fully implanted in a patient as items that penetrate the skin (column 5, lines 29-38). Biocompatible materials appropriate for fabricating implants include metals such as steel and titanium (column 6, lines 22-27). The antimicrobial metal may be silver, gold, platinum, palladium, copper, tin, lead, antimony, bismuth or zinc (column 7, lines 16-18). The antimicrobial metal may be deposited on the biocompatible material such as titanium by contact with a solution including the antimicrobial metal composition. See column 8, lines 16-25.

7. The prior art of record is indicative of the level of skill of one of ordinary skill in the art. It would have been obvious at the time the invention was made to have incorporated a biocidal metal such as silver into the anodized layer of the titanium workpiece of Cooper as taught by

Pickford and Ogle because the risk of infection would have been reduced when the workpiece was used as an implant. Since Cooper teaches using the same anodizing conditions disclosed and claimed by applicant the characteristics of the surface layer of Cooper that is formed by anodizing would have been expected to be the same as those of applicant's layer as recited in claims 13 and 24. It is emphasized that claim 24 is directed to a process. In Hoffer v. Microsoft Corp., 405 F.3d 1326, 1329, 74 USPQ2d 1481, 1483 (Fed. Cir. 2005), the court noted (quoting *Minton v. Nat 'l Ass 'n of Securities Dealers, Inc.*, 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003)) that a "whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.'" See MPEP 2111.04. In claim 24 the characterization of the surface layer is considered to simply express the intended result of the positively recited anodizing step and is not given weight in evaluating the positively recited process steps.

8. With respect to claims 14 and 15, as noted above, Cooper discloses the use of titanium and titanium alloys. See the abstract.

9. With respect to claim 17, Pickford discloses that the biocidal metal ions are absorbed into the oxide or phosphate matrix formed by anodizing. See page 3, lines 33-36 and page 5, lines 14-17. Contact of the anodized implant of Cooper with the solution including the biocidal metal as taught by Ogle at column 8, lines 16-18 would have resulted in absorption of the metal into the oxide or phosphate matrix.

10. With respect to claim 19, Pickford discloses that silver, gold, platinum, and palladium are suitable biocidal materials (page 2, lines 20-28). As noted above, Ogle discloses that the antimicrobial metal may be silver, gold, platinum or palladium (column 7, lines 16-18).

11. With respect to claim 20, anodizing at 100 V as disclosed by Cooper would have been expected to produce an oxide layer with a thickness of 0.14 micrometers in the same manner as it does in applicant's process. See page 5, lines 15-17 of the specification where it is stated that anodizing at 100V produces a film thickness of about 0.14 micrometers. See also page 6, lines 7-11 of the specification.

12. With respect to claim 21, anodizing at 100V for longer than 30 minutes as disclosed by Cooper would have been expected to produce and pores having a diameter of approximately 5 micrometers and depth of approximately 0.4 micrometers. These are the same process conditions claimed by applicant. See page 6, lines 7-16 of the specification.

13. With respect to claim 25, as noted above, both Pickford and Ogle disclose the use of silver as the biocidal metal.

14. With respect to claims 27 and 28, as noted above, Cooper discloses anodizing in an electrolyte comprising phosphoric acid. The concentration may be 5-15 vol% (column 3, lines 19-21). Pickford also shows that the use of a phosphoric acid solution with concentration falling within the range recited by applicant is known (page 5, lines 5-6).

15. With respect to claim 29, Cooper discloses that the presence of halide in the anodizing solution is undesirable since chloride ions tens to create tunnels and pits in the anodized film (column 3, lines 29-31). . It would have been obvious to have controlled the amount of chloride to a small value to avoid the recognized undesirable effects.

16. With respect to claim 31, Pickford discloses that other elements including copper, tin antimony, lead, bismuth and zinc may be used as ions combined into the matrix of oxide or phosphate. See page 2, lines 30-33. As noted above, Ogle discloses that the antimicrobial metal may be copper, tin, lead, antimony, bismuth or zinc (column 7, lines 16-18).

17. Claims 13-15, 17, 19-21, 24, 25, 27, 28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minevski et al (US publication 2004/0121290) in view of Pickford et al (WO 03/089023) or Ogle (US patent 6,267,782).

18. The Minevski et al publication (hereinafter Minevski) is directed to biocompatible implants. The implant comprises an oxide film-forming metal substrate such as titanium or titanium alloy. The alloy may be Ti-6Al-4V. See paragraph [0017]. The implant consists at least partly of a substrate member that has been treated by anodic oxidation in the presence of phosphate. See paragraph [0028]. The implant may be anodized in an aqueous solution of phosphoric acid having a concentration of between about 0.01N and 5.0N. The electric potential may be between about 10volts and about 150 volts, preferably between about 25 and about 100 volts. The implant is anodized for a period of time between about 15 seconds and 2 hours, preferably between about 1 minute and about 30 minutes. See paragraph [0031]. In example 4, implants were anodized at 50 volts for 30 minutes. These are the same anodizing conditions disclosed and claimed by applicant. Because the process steps are the same, the characteristics of the anodized layer of Minevski would have been expected to be the same as those of applicant's layer as recited in claims 13 and 24.

19. The process recited by applicant in independent claim 24 differs from the process of Minevski by reciting adding ions of a biocidal metal by ion exchange. Pickford and Ogle are interpreted and applied as above. It would have been obvious at the time the invention was made to have incorporated a biocidal metal such as silver into the anodized layer of the titanium workpiece of Minevski as taught by Pickford and Ogle because the risk of infection would have been reduced when the workpiece was used as an implant. Since Minevski teaches using the same anodizing conditions disclosed and claimed by applicant the characteristics of the surface layer of Minevski that is formed by anodizing would have been expected to be the same as those of applicant's layer as recited in claims 13 and 24. As stated above, it is emphasized that claim 24 is directed to a process. In Hoffer v. Microsoft Corp., 405 F.3d 1326, 1329, 74 USPQ2d 1481, 1483 (Fed. Cir. 2005), the court noted (quoting *Minton v. Nat 'l Ass 'n of Securities* Dealers, Inc., 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003)) that a "whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.'" See MPEP 2111.04. In claim 24 the characterization of the surface layer is considered to simply express the intended result of the positively recited anodizing step and is not given weight in evaluating the positively recited process steps.

20. With respect to claims 14 and 15, as noted above, Minevski discloses the use of titanium and titanium alloys. See the abstract.

21. With respect to claim 17, Pickford discloses that the biocidal metal ions are absorbed into the oxide or phosphate matrix formed by anodizing. See page 3, lines 33-36 and page 5, lines 14-17. Contact of the anodized implant of Minevski with the solution including the biocidal

metal as taught by Ogle at column 8, lines 16-18 would have resulted in absorption of the metal into the oxide or phosphate matrix.

22. With respect to claim 19, Pickford discloses that silver, gold, platinum, and palladium are suitable biocidal materials (page 2, lines 20-28). As noted above, Ogle discloses that the antimicrobial metal may be silver, gold, platinum or palladium (column 7, lines 16-18).

23. With respect to claim 20, anodizing at 100 V as disclosed by Minevski would have been expected to produce an oxide layer with a thickness of 0.14 micrometers in the same manner as it does in applicant's process. See page 5, lines 15-17 of the specification where it is stated that anodizing at 100V produces a film thickness of about 0.14 micrometers. See also page 6, lines 7-11 of the specification. Minevski additionally discloses that the depth of the phosphorus and oxygen penetration is between about 0.05 μm and about 0.5 μm (paragraph [0035]). Applicant's film thickness falls within this range.

24. With respect to claim 21, anodizing at 100V for about 30 minutes or longer as disclosed by Minevski would have been expected to produce and pores having a diameter of approximately 5 micrometers and depth of approximately 0.4 micrometers. These are the same process conditions claimed by applicant. See page 6, lines 7-16 of the specification.

25. With respect to claim 25, as noted above, both Pickford and Ogle disclose the use of silver as the biocidal metal.

26. With respect to claims 27 and 28, as noted above, Minevski discloses anodizing in an electrolyte comprising phosphoric acid. The aqueous solution of phosphoric acid may have a concentration of between about 0.01N and 5.0N (paragraph [0031]). Pickford also shows that

the use of a phosphoric acid solution with concentration falling within the range recited by applicant is known (page 5, lines 5-6).

27. With respect to claim 31, Pickford discloses that other elements including copper, tin antimony, lead, bismuth and zinc may be used as ions combined into the matrix of oxide or phosphate. See page 2, lines 30-33. As noted above, Ogle discloses that the antimicrobial metal may be copper, tin, lead, antimony, bismuth or zinc (column 7, lines 16-18).

28. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Minevski et al (US publication 2004/0121290) in view of Pickford et al (WO 03/089023) or Ogle (US patent 6,267,782) as applied to claims 13-15, 17, 19-21, 24, 25, 27, 28 and 31above, and further in view of Rosenberg et al (US 5,185,075).

29. Claim 29 recites that the electrolyte comprises chloride ions at a concentration no more than 500 ppm. The Rosenberg et al patent is directed to a process for anodizing titanium and titanium alloy articles. Table 1 shows that a 5-25 vol % solution of phosphoric acid is a useful anodizing electrolyte. Rosenberg recognizes that halides may be harmful to the anodizing process and suggests the addition of silver nitrate to suppress free chloride. When using silver nitrate for this purpose, the appearance of the yellow silver phosphate signals the excess of silver over halide (column 5, lines 58-63). It would have been obvious to have controlled the amount of chloride to a small value in the anodizing process of Minevski because Rosenberg teaches than an excessive amount may be harmful to the anodizing process.

Claim Rejections - 35 USC § 112

30. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

31. Claims 13-15, 17, 19-21, 24, 25, 27-29 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Independent claim 24 recites anodizing for forming a surface layer integral with the titanium metal substrate at a voltage above 50 volts for a period of at least 30 minutes. Applicant recites that this anodizing generates a dense hard surface layer with shallow pits in the surface layer which are filled with a somewhat softer and more porous material comprising titanium oxide, wherein the surface layer comprises a surface area, and wherein the pits have of a diameter about 5 microns and occupy between 15 and 20% of the surface area of the surface layer, the pits extending through the hard layer into the metal substrate, such that in the ion exchange step the more porous material in the pits absorbs biocidal metal to a larger extent than the hard layer. However, it is not apparent that control of the two recited anodizing process parameters of voltage and time to be within the ranges recited lead to the formation of a surface layer having the characteristics recited in claim 24 or in claim 13. By not more specifically setting forth the required process parameters, applicant has failed to enable the production of the surface layer recited in claims 13 and 24.

Double Patenting

32. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

33. Claims 24, 25, 27-29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 12/539,028 in view of Cooper et al (US 5,211,832) or Minevski et al (US publication 2004/0121290). Claims 1 of the '028 applicant recites a method of making an implant including the steps of anodizing to form an integral surface layer, rinsing and absorbing biocidal metal ions into the surface layer. Claim 24 of the instant application differs from the process recited in the '028 application by reciting that the anodizing was conducted at a voltage above 50 volts for a period of at least 30 minutes. As discussed above, Cooper and Minevski disclose the use of these anodizing parameters in the formation of a surface layer on an implant. It would have been obvious to have performed the anodizing step in the process of the '028 application at a voltage above 50 volts for a period of at least 30 minutes as taught by Cooper or Minevski because a corrosion resistant surface would have been formed.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

34. Applicant's arguments filed January 13, 2011, have been fully considered but they are not persuasive. The arguments with respect to the rejection over Pickford in view of O'Brien are moot in view of the current grounds of rejection. At page 9 of the Remarks, applicant points out that claims 13 and 24 recite characteristics of the surface layer of the implant, and in particular points out that claims 13 and 24 recite that the pits extend through the hard layer into the metal substrate. Applicant argues that, to the contrary, Cooper teaches anodizing in such a way to

produce an oxide layer that is protective of the underlying surface. This argument is not convincing. In examples 6, 7 and 8 Cooper utilized anodizing process parameters for voltage and time which fall within the ranges recited by applicant. Thus, Cooper performs the anodizing in the same way as claimed by applicant. Applicant has offered no explanation as to why the surface layer produced by applicant has different characteristics than that of Cooper when they are both formed in the same way. Additionally, as stated above, in claim 24 the characterization of the surface layer is considered to simply express the intended result of the positively recited anodizing step and is not given weight in evaluating the positively recited process steps.

35. In the paragraph bridging pages 9 and 10 of the Remarks, applicant points to column 4, lines 17-24 of Cooper and additionally refers to the sensitivity of certain characteristics of the materials produced using the process of Cooper. Applicant argues that these portions of Cooper are inconsistent with an expectation that the product and process of Cooper teach or suggest the recitations of claim 13 and 24. As explained above, the process taught by Cooper for anodizing titanium is the same anodizing process claimed by applicant. If one were to accept the argument that there is no expectation that the anodizing process taught by Cooper teaches or suggests a product as recited in claims 13 and 24, one would similarly have to conclude that there is no expectation that applicant's claimed process would lead to the recited product since the anodizing processes are the same. Such a conclusion would appear to be contrary to applicant's specification which indicates that by carrying out the anodizing process recited in claim 24, a product with the specified characteristics is obtained. See page 6, lines 6-16 of the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM T. LEADER whose telephone number is (571) 272-1245. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alexa D. Neckel can be reached on 571-272-1446. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William Leader/
February 25, 2011

/Alexa D. Neckel/

Supervisory Patent Examiner, Art Unit 1723